REMARKS

Claims 50-55 have been *renumbered* to claims 49-54 to correct an obvious misnumbering in the previously presented claims. (*See* Paper No. 0607 at 2.)

Claims 29, 37, 50-52 have been cancelled, without prejudice.

Claims 25-28, 35-36, 42-43, 46-47, and 54 have been amended to recite compositions comprising "epigallocatechin gallate (EGCG)," "pantethine," and "phytanic acid." Support for these amendments is found in the specification at, for example, page 1, lines 1-15; page 1, line 19 – page 2, line 2; page 3, lines 20-23; page 4, line 1 – page 5, line 26; and page 6, line 3 – page 8, line 7; in Examples 1-11; and in original claims 5 and 23. *See In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01(o) and (l) (8th ed. Rev. 5, August 2006, pp. 600-92 and 600-84).

In view of these amendments, claims 34 and 41 have been amended to correct dependency.

Claim 41 has been amended to properly refer to the subject matter of the claims upon which it depends, *i.e.*, the unit dosage form.

It is submitted that no new matter has been introduced by the foregoing amendments. Approval and entry of the amendments is respectfully solicited.

Rejection under 35 USC § 102

Claims 42-44 were rejected under 35 USC § 102(e) as anticipated by Gorsek, US Patent No. 6,565,896 ("Gorsek".) (Paper No. 0607 at 4.)

For the reasons set forth below, the rejection respectfully is traversed.

Gorsek discloses "Gamma Oryzanol, Guglipids, Beta Sitosterol, Green Tea extract, Artichoke extract, Grape Seed extract, Chromium, Pantethine, Policosanol, as well as other healthy filler ingredients." Col. 1, lines 30-33. Moreover, Gorsek discloses that "the key to the unique formulation is a combination of specific vitamins, minerals, herbs and nutrients. These ***essential components*** in the amounts provided uniquely contribute to a healthier cholesterol count in the bloodstream." Col. 1, lines 24-29 (emphasis added).

In making the rejection, the Examiner asserted that Gorsek discloses "a composition which comprises EGCG and pantethine." (Paper No. 0607 at 4.)

Initially, we note that independent claims 42-43 have been amended to recite a "composition comprising epigallocatechin gallate (EGCG), pantethine, and phytanic acid in admixture with a food or beverage."

As is well settled, anticipation requires "identity of invention." *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply,* 33 USPQ2d 1496, 1498 (Fed. Cir. 1995). Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim. *In re Marshall*, 198 USPQ 344, 346 (CCPA 1978); *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.,* 221 USPQ 481, 485 (Fed. Cir 1984).

Claims 42-43 have been amended to further prosecution. Claims 42-43 recite compositions comprising **(1)** "epigallocatechin gallate (EGCG)," **(2)** "phytanic acid," and **(3)** "pantethine" "in admixture with a food or beverage."

Gorsek discloses "a combination of specific vitamins, minerals, herbs and nutrients [that] in the amounts provided uniquely contribute to a healthier cholesterol

count in the bloodstream." Col. 1, lines 24-29. This combination is "Gamma Oryzanol, Guglipids, Beta Sitosterol, Green Tea extract, Artichoke extract, Grape Seed extract, Chromium, Pantethine, Policosanol, as well as other healthy filler ingredients." Col. 1, lines 30-33.

Gorsek does not disclose compositions comprising **(1)** "epigallocatechin gallate (EGCG)," **(2)** "phytanic acid," and **(3)** "pantethine" "in admixture with a food or beverage." Accordingly, Gorsek does not disclose the compositions as claimed.

Gorsek also does not disclose any food or beverage composition. Accordingly, Gorsek does not disclose anything in admixture with a food or beverage, much less a composition comprising "epigallocatechin gallate (EGCG)," "phytanic acid," and "pantethine" "in admixture with a food or beverage," as claimed.

In addition, Gorsek is completely silent as to the treatment or reduction of the risk or incidence of type 2 diabetes. Accordingly, Gorsek does not disclose treating or reducing the incidence or risk of diabetes type 2 in a human by administering a composition currently claimed.

Thus, the rejection does not demonstrate where in Gorsek each and every element of the claimed invention is disclosed. Accordingly, the rejection is deficient for failing to set forth a *prima facie* case for anticipation and should be withdrawn.

Rejections under 35 USC § 103

Claims 25-55 were rejected under 35 USC § 103(a) as being unpatentable over Chan, U.S. Patent No. 5,922,756 ("Chan"), Fluehmann *et al.*, U.S. Patent No. 6,784,207 ("Fluehmann"), and Cincotta *et al.*, U.S. Patent No. 5,714,519 ("Cincotta"). (Paper No. 0607 at 6.)

For the reasons set forth below the rejection, respectfully, is traversed.

Chan discloses "a pharmacologically acceptable composition for inhibiting nitric oxide synthase (NOS) in a mammal ... include[ing] a catechin derivative and a pharmaceutically acceptable carrier, with the active agent present in the composition in an effective amount to inhibit NOS in the mammal." Col. 2, lines 31-37. Chan discloses EGCG as a catechin derivative useful in its invention. *See, e.g.*, claims 1 and 7. Chan also discloses that "an NO synthase enzyme may be involved in the pathophysiology of autoimmune and/or inflammatory conditions such as arthritis, rheumatoid arthritis and systemic lupus erythematosus and in insulin-dependent diabetes mellitus, and therefore, catechin derivatives may prove helpful in treating these conditions." Col. 3, lines 50-55.

Fluehmann discloses a "method for the treatment or prevention of preferably non-insulin dependent (NIDDM or so-called Type II) diabetes mellitus, and in particular to the use of phytanic acid derivatives for the treatment or prevention of NIDDM." Col. 1, lines 11-15. Fluehmann discloses that "NIDDM is the form of diabetes mellitus that occurs predominantly in adults in whom adequate production of insulin is available for use, yet a defect exists in insulin-mediated utilization and metabolism of glucose in peripheral tissues." Col. 1, lines 16-20. Fluehmann also discloses that phytanic acid and/or phytenic acid or derivatives thereof have the effect of "decreasing hyperinsulinaemia."

Cincotta discloses that an "object of the invention is to correct abnormalities in the glucose metabolism of a vertebrate animal, including humans, by administering an effective amount for: decreasing glucose intolerance; decreasing

hyperinsulinemia; decreasing insulin resistance; and/or decreasing hyperglycemia of pantethine or cysteamine." Col. 3. lines 60-65. Cincotta discloses that the "foregoing objects are accomplished by administering pantethine to a vertebrate subject in need of such treatment in an effective amount to reduce or ameliorate one or more aberrant indices associated with metabolism disorders (e.g., reducing glucose intolerance, reducing insulin resistance, reducing hyperglycemia, reducing hyperinsulinemia, ameliorating or treating Type II diabetes, and reducing levels of body fat)." Col. 4, lines 26-34.

In making the rejection, the Examiner asserted that Chan discloses that "EGCG is an inhibitor of nitric oxide synthase ... [and] that an NO synthase may be involved in diabetes and therefore, catechin derivative (including EGCG may be helpful in treating the condition." (Paper No. 0607 at 6.) The Examiner also asserted that Chan discloses "a method of treating diabetes which comprises administering to a mammal in need thereof EGCG." (*Id.*)

The Examiner acknowledged, however, that Chan differs from the presently claimed invention in that "Chan does not [disclose] that phytanic acid or pantethine are included in this composition." (*Id.*)

To fill the acknowledged gap, the Examiner relied upon Fluehmann as disclosing "a composition for the treatment of diabetes [including] phytanic acid, a method of making the composition ...[,] and a method for the treatment of diabetes using phytanic acid ...." (*Id.* at 7.)

Also to fill the acknowledged gap, the Examiner relied upon Cincotta as disclosing "a method for the treatment of diabetes [including] administering to a subject in need thereof an effective amount of pantethine." (*Id.*)

The Examiner then concluded that "[i]t would have been obvious ... to admix EGCG, pantethine, phytanic acid, and mixtures thereof in the dosage forms and amounts instantly claimed in order to make a composition for the treatment of diabetes." (*Id.*)

With a view towards furthering prosecution, claims 25-28, 35-36, 42-43, 46-47, and 54 have been amended to recite compositions, neutraceutical compositions, unit dosage forms for treating or reducing the incidence or risk of type 2 diabetes, a method for treating or reducing the incidence or risk of type 2 diabetes, or a method for treating diabetes that may be type 1 diabetes by administering a composition, where the composition, neutraceutical composition, or unit dosage form comprises epigallocatechin gallate (EGCG), ***pantethine,*** and phytanic acid.

It is well settled that the Examiner bears the burden to set forth a *prima facie* case of unpatentability. *In re Glaug*, 62 USPQ2d 1151, 1152 (Fed. Cir. 2002); *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); and *In re Piasecki*, 223 USPQ 785, 788 (Fed. Cir. 1984). If the PTO fails to meet its burden, then the applicant is entitled to a patent. *In re Glaug*, 62 USPQ2d at 1152.

When patentability turns on the question of obviousness, as here, the search for and analysis of the prior art by the PTO should include evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to do what the Applicants have done. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, 82

USPQ2d 1385, 1396 (April 30, 2007) (the obviousness "***analysis should be made explicit***" and the teaching-suggestion-motivation test is "***a helpful insight***" for determining obviousness) (emphasis added); *McGinley v. Franklin Sports*, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001). Moreover, the factual inquiry whether to modify documents must be thorough and searching. And, as is well settled, the teaching, motivation, or suggestion to combine "***must be based on objective evidence of record***." *In re Lee*, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002) (emphasis added). *See also* Examination Guidelines for Determining Obviousness, 72 Fed. Reg. 57526, 57528 (October 10, 2007) ("the U.S. Patent and Trademark Office Examination Guidelines") ("The key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious.").

The rejection is devoid of a proper §103 analysis. All that is there are conclusory statements such as: (1) "[i]t would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to admix EGCG, pantethine, phytanic acid and mixtures thereof in the dosage forms and amounts instantly claimed in order to make a composition for the treatment of diabetes", (2) "[o]ne of ordinary skill in the art would have been motivated to [do] so based upon the disclosures of Chan, [Fluehmann], and [Cincotta] that EGCG, phytanic acid and pantethine are useful in the treatment of diabetes in the same ranges of dose amounts and in the same forms instantly claimed", and (3) "[i]t would have been obvious to administer such a composition to a subject in need of treatment for diabetes, especially in view of the disclosure of methods for treatment disclosed by Chan, [Fluehmann], and

[Cincotta] which comprise administration of each component of the instantly claimed composition to a subject in need of diabetes treatment." (Paper No. 0607 at 7-8).

What the rejection should have done, but did not, was to explain on the record ***why*** one skilled in this art would modify the disclosure of Chan with Fluehmann, and Cincotta to arrive at the claimed composition. As is well settled, an Examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done. *Takeda Chem. Indus., Ltd v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. June 28, 2007) (indicating that "it remains necessary to identify ***some reason*** that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound") (emphasis added); *Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993). But this is precisely what the Examiner has done here. Thus, the rejection is legally deficient and should be withdrawn for this reason alone.

Notwithstanding the legally insufficient nature of the rejection, we note that the rejection is also factually insufficient to support a rejection under § 103(a). In doing so we observe that obviousness cannot be based upon speculation, nor can obviousness be based upon possibilities or probabilities. Obviousness ***must*** be based upon facts, "cold hard facts." *In re Freed*, 165 USPQ 570, 571-72 (CCPA 1970). When a conclusion of obviousness is not based upon facts, it cannot stand. *Ex parte Saceman*, 27 USPQ2d 1472, 1474 (BPAI 1993). Further, "to establish *prima facie* obviousness of a claimed invention, ***all claim limitations must be taught or***

suggested by the prior art." MPEP § 2143.03 (citing *In re Royka*, 180 USPQ 580 (CCPA 1974)) (emphasis added).

Beyond looking at the references to determine if any of them suggests doing what the inventors have done, one must also consider if the art provides the required expectation of succeeding in that endeavor. See *In re Dow Chem. Co. v. American Cyanamid Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988) ("Both the suggestion and the expectation of success must be founded in the prior art, not in applicants' disclosure.") "Obviousness does not require absolute predictability, but a reasonable expectation of success is necessary." *In re Clinton*, 188 USPQ 365, 367 (CCPA 1976). Furthermore, the U.S. Patent and Trademark Office Examination Guidelines at page 57527 provide the following guidance to Examiners: "In short, the focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on what such a person would have reasonably expected to have been able to do in view of that knowledge".

However, no such motivation or expectation of success can be found in the cited documents.

Chan discloses "a pharmacologically acceptable composition for inhibiting nitric oxide synthase (NOS) in a mammal ... include[ing] a catechin derivative and a pharmaceutically acceptable carrier, with the active agent present in the composition in an effective amount to inhibit NOS in the mammal." Col. 2, lines 31-37. Chan discloses EGCG as a catechin derivative useful in its invention. *See, e.g.*, claims 1 and 7. Chan discloses that the catechin derivatives "may be useful to inhibit NO synthesis in patients suffering from inflammatory conditions in which an excess of NO contributes

to the pathophysiology of the condition, such as adult respiratory distress syndrome and myocarditis, for example." Col. 3, lines 45-49. The only reference to diabetes in Chan is to type 1 diabetes (insulin-dependent diabetes mellitus):

> an NO synthase enzyme may be involved in the pathophysiology of ***autoimmune and/or inflammatory conditions*** such as arthritis, rheumatoid arthritis and systemic lupus erythematosus and in ***insulin-dependent diabetes mellitus***, and therefore, catechin derivatives may prove helpful in treating these conditions. Col. 3, lines 50-55.

Moreover, Chan provides a "laundry list" of potential indications for which ECGC could be implicated, spanning from Col. 3 line 51 to Col. 4, line 17. Chan's only reference to diabetes in the specification, however, as indicated above, pertains to "autoimmune and/or inflammatory conditions such as ... insulin-dependent diabetes mellitus..." Col. 3, lines 52-55.. The next paragraph of the specification refers to "a number of additional inflammatory and non-inflammatory diseases that are associated with NO over-production." Col. 3, lines. 57-59. The subsequent "laundry list" of diseases does not include diabetes type 2. In view of the broad and generic introduction to the list of "additional inflammatory and non-inflammatory diseases", diabetes type 2 is noticeably absent. Also in view of this disclosure, one skilled in the art would consider Chan to teach the possibility of affecting ***type 1*** diabetes.

In type 1 diabetes, the pancreas no longer makes insulin because the beta cells have been destroyed. Accordingly, the body does not produce its own insulin, resulting in hypoinsulinaemia.[1] Thus, an exogenous source of insulin is generally

[1] Hyperinsulinaemia is defined as "an abnormally low concentration of insulin in the blood." Merriam-Webster's Medical Dictionary, Merriam-Webster, Inc. (2002).

required to utilize glucose from food. *See*, *e.g.*, the American Diabetes Association website (http://www.diabetes.org).

Fluehmann discloses a "method for the treatment or prevention of preferably ***non-insulin dependent (NIDDM or so-called Type II) diabetes mellitus***, and in particular to the use of phytanic acid derivatives for the treatment or prevention of NIDDM." Col. 1, lines 11-15. Fluehmann discloses that "NIDDM is the form of diabetes mellitus that occurs predominantly in adults ***in whom adequate production of insulin is available for use,*** yet a defect exists in insulin-mediated utilization and metabolism of glucose in peripheral tissues." Col. 1, lines 16-20. Fluehmann also discloses that phytanic acid and/or phytenic acid or derivatives thereof have the effect of "***decreasing hyperinsulinaemia***."[2]

Cincotta discloses that an "object of the invention is to correct abnormalities in the glucose metabolism of a vertebrate animal, including humans, by administering an effective amount for: decreasing glucose intolerance; ***decreasing hyperinsulinemia***; decreasing insulin resistance; and/or decreasing hyperglycemia of pantethine or cysteamine." Col. 3. lines 60-65. Cincotta discloses that the "foregoing objects are accomplished by administering pantethine to a vertebrate subject in need of such treatment in an effective amount to reduce or ameliorate one or more aberrant indices associated with metabolism disorders (e.g., reducing glucose intolerance, reducing insulin resistance, reducing hyperglycemia, ***reducing hyperinsulinemia***, ***ameliorating or treating Type II diabetes***, and reducing levels of body fat)." Col. 4,

[2] Hypoinsulinaemia is defined as "the presence of excess insulin in the blood." Merriam-Webster's Medical Dictionary, Merriam-Webster, Inc. (2002).

lines 26-34. In the only reference to type 1 diabetes, Cincotta contrasts it with type 2 diabetes:

> In insulin-dependent (IDDM or Type I) diabetes, wherein the pancreas produces little or no insulin, insulin must be injected daily. In noninsulin-dependent (NIDDM or Type II) diabetes ***the pancreas retains the ability to produce insulin, in fact it may produce higher than normal amounts of insulin (hyperinsulinemia)***, but due to a cellular resistance to insulin, the amount of insulin is relatively insufficient. Col. 1, lines 47-54.

To summarize, Chan discloses that a catechin derivative, such as EGCG, may help in the treatment of autoimmune and inflammatory disorders, including type 1 diabetes. Fluehmann and Cincotta disclose that phytanic acid (and derivatives) or pantethine, respectively, may be used to decrease hyperinsulinaemia and treat type 2 diabetes. Thus, Chan provides a way to increase the production of insulin in those who lack the ability to produce insulin. And, Fluehmann and Cincotta provide a way to decrease blood levels of insulin in type 2 diabetics who have insulin resistance.

The disclosures of Chan, Fluehmann, and Cincotta provide no motivation to provide compositions, neutraceutical compositions, unit dosage forms for treating or reducing the incidence or risk of type 2 diabetes, or methods for treating or reducing the incidence or risk of type 2 diabetes, or a method for treating diabetes that may be type 1 diabetes by administering a composition, where the composition, neutraceutical composition, or unit dosage form comprises epigallocatechin gallate (EGCG), pantethine, and phytanic acid. Based on the disclosures of Chan, Fluehmann, and Cincotta, it would defy common sense to consider administering EGCG and phytanic acid and pantethine concomitantly. According to Chan, EGCG would potentially increase insulin blood levels in type 1 diabetics. According to Fluehmann and Cincotta

phytanic acid and pantethine, respectively, work to decrease hyperinsulinaemia in type 2 diabetics. Thus, according to the cited documents, one skilled in the art would not expect success in the formulation of or administration of EGCG concomitantly with phytanic acid and pantethine.

The Examiner, in asserting that in view of the arguments submitted in the prior Response that since "it would have been futile to combine the components in order to treat both type I and type II diabetes, Applicants invention would not be enabled", the Examiner makes a number of errors. The Examiner misconstrues what was argued. An examination of the teachings of the references tends to lead one of skill in the art away from such a combination rather than suggesting it for the treatments claimed. Applicants have indicated, and maintain here, that Chan, alone or in combination with any or all of the secondary references, does not provide motivation to formulate or administer a composition comprising ECGC, pantethenic acid and phytanic acid for the indications claimed. The Examiner's statement suggesting lack of enablement is misapplied since the Examiner has misconstrued Applicants' arguments. For clarity here, it is noted that no rejection on the basis of lack of enablement has been made in the Action.

It remains for the Examiner to apply what the U.S. Patent and Trademark Office Examination Guidelines state should be "the focus when [analyzing obviousness]" – to consider "what [a person of ordinary skill in the pertinent art] would have reasonably expected to have been able to do" in view of the knowledge at the time the application was filed. One skilled in the art would not

have thought to combine the references or the individual components EGCG, pantethine and phytanic acid to provide compositions, neutraceutical compositions, unit dosage forms, or methods of treatment for treating the claimed indications given a lack of expectation of success in the same.

The Examiner's only purported factual basis for support of the rejection hinges on the statement that "[Cincotta] teach that patients of both type I and type II diabetes may share the problem of insulin resistance (see e.g. col. 1, lines 47-56)". Although Applicants do not concede that that the cited portion of Cincotta teaches what what the Examiner alleges that it does, Applicants submit that any potential suggestion in relation treatment of insulin resistance still does not provide teaching, suggestion or motivation to provide a composition, neutraceutical composition, unit dosage form, or a method of treatment using such a composition for treating diabetes type 1 or type 2 for the reasons stated above. And in addition, Cincotta provides no suggestion that insulin resistance in type 1 or type 2 patients could be treated in the claimed manner. One skilled in the art, giving a fair reading to Cincotta, alone or in combination with the other references, would not have reasonably expected to achieve success in the invention as claimed.

Thus, there is nothing in the cited documents that discloses or suggests their combination as suggested by the Examiner. In fact, the cited documents tend to teach one skilled in the art away from such combination. Accordingly, the rejection fails to present a *prima facie* case for obviousness and should be withdrawn.

In addition, regarding claims 42, 43 and claims dependent thereon, none of the references Chan, Fluehmann, nor Cincotta, disclose or suggest a composition

that is formulated as a food or beverage. The rejection as to these claims cannot stand.

Claim 45 was rejected under 35 USC § 103(a) as being unpatentable over Chan, Fluehmann, Cincotta, Fischer, US Patent No. 5,599,835 ("Fischer"), Pistolesi, WO 02/052955 A1 ("Pistolesi"), and Eriksson *et al.*, Biofactor, vol. 9, pp. 315-318 (1999) ("Eriksson"). (Paper No. 0607 at 9.)

For the reasons set forth below the rejection, respectfully, is traversed.

Chan, Fluehmann, and Cincotta are summarized above.

Fischer discloses a "method for the management of a metabolic disorder expressed as diabetes mellitus, which is a syndrome of impaired carbohydrate, protein and fat metabolism secondary to insufficient secretion of insulin." Col. 2, lines 54-57. Fischer discloses that the "use of DL-lipoic acid in co-administration with other nutrients that are also essential to the multi-enzyme reactions of the pyruvate dehydrogenase complex ... [and] a composition as a modular-formula medical food for oral administration [for] the treatment, management or correction of a metabolic disorder that is indicative of diabetes mellitus." Col. 2, lines 58-65.

Pistolesi discloses "pharmaceutical and dietary compositions ... for both preventing and treating aging processes and related conditions" including diabetes. p. 1. Pistolesi further discloses that its "compositions [include]:

a) a lipidic mixture rich in polyunsaturated fatty acids, preferably docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA), conjugated linoleic acids (CLA) and y-linolenic acid, and antioxidant vitamins, in combination with at least two of the following components:

b) one or more terpenes, selected from monoterpenes and/or sesquiterpenes, triterpenes, lactonic terpenes, but preferably monoterpenes or sesquiterpenes,

c) 1-piperoylpiperidine (in pure form and/or purified extracts or fractions containing it enriched in black pepper) and/or capsaicin and analogues thereof, preferably 1- piperoylpiperidine,

d) one or more polycosanols and/or polycosanolic acids. p. 1.

Eriksson discloses that Coenzyme Q_{10} has "no major effect ... on metabolic parameters in diabetics." p. 318. Eriksson concluded "that treatment with CoQ_{10} is well tolerated among type 2 diabetics and that CoQ_{10} does not interfere with the glycemic control, i.e., CoQ_{10} is neutral with respect to diabetes control. Therefore, CoQ_{10} may be used safely in type 2 diabetes, and especially in association with arterial hypertension, coronary artery disease or heart failure CoQ_{10} may contribute to potential long term benefits in the treatment of type 2 diabetic patients." (*Id.*)

In making the rejection, the Examiner asserted that Chan, Fluehmann, and Cincotta disclose "compositions and methods for the treatment of diabetes comprising EGCG, phytanic acid and pantethine and are relied upon for the reasons set forth above." (Paper No. 0607 at 10.)

The Examiner apparently recognized that the suggested combination of Chan, Fluehmann, and Cincotta differs from the presently claimed invention in that the combination does not disclose a composition containing lipoic acid, policosanol and coenzyme Q-10.

To fill this gap, the Examiner relied upon Fischer as disclosing "lipoic acid as a treatment for diabetes ... [and] a method for the treatment of diabetes comprising administering to a person in need thereof an effective amount of a medicinal food [including] lipoic acid." (*Id.*)

Also to fill this gap, the Examiner relied upon Pistolesi as disclosing "a composition for treating aging processes and related [conditions], including diabetes ... the composition [including] policosanol." (*Id.*)

In addition, to fill this gap, the Examiner relied on Eriksson as disclosing "the use of coenzyme Q_{10} in a treatment for diabetes." (*Id.*)

The Examiner then concluded that "[i]t would have been obvious ... to combine the ingredients [disclosed] by Chan, Fluehmann et al., Cincotta et al., Fischer, Pistolesi, and Eriksson to make a food or beverage [including] EGCG, pantethine, phytanic acid, lipoic acid, policosanol and coenzyme Q_{10}." (*Id.*)

In Response to Applicants' arguments filed April 13, 2007, the Examiner asserted that "Applicants argue that it would not be obvious to further add, lipoic acid, policosanol and coenzyme Q_{10} to a composition in order to treat diabetes as instantly claimed. This is not persuasive, however, as Fischer, Pistolesi, and Eriksson each teach that lipoic acid, policosanol and coenzyme Q_{10} are useful in treating diabetes." (*Id.* at 11).

When patentability turns on the question of obviousness, as here, the search for and analysis of the prior art by the PTO should include evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to do what the Applicants have done. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (April 30, 2007) (the obviousness "***analysis should be made explicit***" and the teaching-suggestion-motivation test is "***a helpful insight***" for determining obviousness) (emphasis added); *McGinley v. Franklin Sports*, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001). Moreover, the factual inquiry whether to modify

documents must be thorough and searching. And, as is well settled, the teaching, motivation, or suggestion to combine "***must be based on objective evidence of record***." *In re Lee*, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002) (emphasis added). *See also* Examination Guidelines for Determining Obviousness, 72 Fed. Reg. 57526, 57528 (October 10, 2007) ("the U.S. Patent and Trademark Office Examination Guidelines") ("The key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious.").

As discussed above, Chan provides a way to increase the production of insulin in those who lack the ability to produce insulin. And, Fluehmann and Cincotta provide a way to decrease blood levels of insulin in type 2 diabetics who have insulin resistance.

Based, on the disclosures of Chan, Fluehmann, and Cincotta it would defy common sense to administer EGCG and phytanic acid or pantethine concomitantly. According to Chan, EGCG would potentially increase insulin blood levels in type 1 diabetics. According to Fluehmann and Cincotta phytanic acid and pantethine, respectively, work to decrease hyperinsulinaemia in type 2 diabetics. One skilled in the art would not have thought to combine the references or the individual components EGCG, pantethine and phytanic acid to provide compositions, neutraceutical compositions, unit dosage forms, or methods of treatment for treating the claimed indications given a lack of expectation of success in the same.

Nothing in the newly cited documents, *e.g.*, Fischer, Pistolesi, and/or Eriksson offers anything to close this fatal gap in the combination of Chan, Fluehmann, and Cincotta. Thus, as with the previous rejection, there is nothing in the cited

documents that discloses or suggests their combination as suggested by the Examiner. In fact, the cited documents tend to teach one skilled in the art away from such combination. Accordingly, the rejection fails to present a *prima facie* case for obviousness and should be withdrawn.

Provisional Obviousness-Type Double Patenting Rejections

Claims 46-47, 50, 52-53, and 55 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting. (Paper No. 0607 at 3.) In making the rejection, the Examiner alleged that claims 46-47, 50, 52-53, and 55 of the instant application are "unpatentable over claims 10-13 of copending Application No. 10/766,118." (*Id.*)

Claims 25-50 and 52-55 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting. (Paper No. 0607 at 3.) In making the rejection, the Examiner alleged that claims 25-50 and 52-55 of the instant application are "unpatentable over claims 8-18 of copending Application No. 10/573,222." (*Id.*)

Claims 25-45 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting. (Paper No. 0607 at 3.) In making the rejection, the Examiner alleged that claims 25-45 of the instant application are "unpatentable over claims 1-8 of copending Application No. 10/588,042." (*Id.*)

Claims 25-47 and 50-55 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting. (Paper No. 0607 at 3.) In making the rejection, the Examiner alleged that claims 25-47 and 50-55 of the instant

application are "unpatentable over claims 1-9 of copending Application No. 10/536,374." (*Id.*)

Claims 25-55 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting. (Paper No. 0607 at 4.) In making the rejection, the Examiner alleged that claims 25-55 of the instant application are "unpatentable over claims 1-8, 18-20 and 26-27 of copending Application No. 10/525,348." (*Id.*)

Initially, we note that claims 29, 37, 50-52 have been cancelled, without prejudice. Thus, all of the provisional double patenting rejections have been rendered moot with respect to these claims and should be withdrawn.

We also note that claims 25-28, 35-36, 42-43, 46-47, and 54 have been amended to recite compositions comprising "epigallocatechin gallate (EGCG)," "pantethine," and "phytanic acid."

We further note that an obviousness-type double patenting analysis is an obviousness analysis, and it must follow and be based on each of the *Graham* factors. *See Studiengesellschaft Kohle mbH v. Northern Petrochemical Co.*, 228 USPQ 837, 840, *cert. dismissed*, 478 U.S. 1028 (1986); and *Pac-Tec, Inc. v. Amerace Corp.*, 14 USPQ2d 1871, 1876 (Fed. Cir. 1990); *In re Braat*, 19 USPQ2d 1289, 1292 (Fed. Cir. 1991); *In re Braithwaite*, 154 USPQ 29, 34 n. 4 (CCPA 1967).

Thus, as explained in MPEP § 804 at p. 800-21 to p. 800-22, an obviousness-type double patenting rejection must make clear:

> (A) ***The differences between the inventions*** defined by the conflicting claims - ***a claim*** in the patent ***compared to a claim*** in the application; and

> (B) ***The reasons why a person of ordinary skill in the art*** would conclude that the invention defined in ***the claim*** at issue ... would have been an obvious variation of the invention defined in ***a claim*** in the patent.

As the Office Action reflects, while the Examiner acknowledged that the pending claims were different from the claims of the '118, '222, '042, '374, and '348 applications, the rejections unabashedly ignore the remaining requirements for a proper rejection for obviousness. Specifically, there is no mention of ***why*** one of ordinary skill in the art, with the claims of the '118, '222, '042, '374, and '348 applications, would have been motivated to select and arrive at the currently claimed compositions. But the PTO ***must*** make findings -- based on factual objective evidence -- "as to the specific understanding or principle within the knowledge of a skilled artisan ***that would have motivated one with no knowledge of [the claimed] invention to make the combination in the manner claimed."*** *See In re Kotzab*, 55 USPQ2d 1313, 1318 (Fed. Cir. 2000). And a conclusion of obviousness ***must*** be based on objective evidence that is clear and particular. *See In re Lee*, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002). That is because obviousness must be based on facts – "cold hard facts." *Freed,* 165 USPQ at 571-72. When a conclusion of obviousness is not based on facts it cannot stand. *Saceman*, 27 USPQ2d at 1474.

In addition, the PTO is ***required to specifically identify each difference*** between ***a claim***, on the one hand, and the disclosure of a reference or ***a claim*** of a reference that is relied upon, on the other. *See Ex parte Rozzi*, 63 USPQ2d 1196, 1201 (BPAI 2002) ("the Examiner has not cogently explained how Hill renders the subject matter of claim 1 obvious within the meaning of 35 USC § 103(a). A major difficulty

with the rejection is that the PTO has failed to make a finding with respect to a difference, if any, between the subject matter of claim 1 and Hill."). As explained in *Ex parte Braeken*, 54 USPQ2d 1110, 1112-13 (BPAI 1999) (unpublished), in making any art based rejection, the PTO must (1) identify all differences between each claim and the disclosure of a reference relied upon, and (2) explain why the subject matter of the claim, as a whole, would have been obvious notwithstanding the differences:

> The Examiner acknowledges that there are differences between the subject matter of the claims and Christenson. Finding 5. But, the Examiner does not articulate with any particularity the precise nature of those differences. We decline to search the Christenson patent to ferret out those differences. ***Rather, findings with respect to the differences between claimed subject matter and the prior art are the responsibility of the Examiner in the first instance***. [At 1112].
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> * * *
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> ***After all differences are identified, the Examiner should then explain why the subject matter of the claim, as a whole, would have been obvious notwithstanding the difference or differences***. Until the differences are identified and the Examiner explains why the claimed subject matter, as a whole, would have been obvious, the appeal is not ripe for decision. [At 1113].

The above requirements, of course, also apply to double patenting rejections. *Ortho Pharmaceutical Corp. v. Herchel Smith*, 22 USPQ2d 1119 (Fed. Cir. 1992) (a "double patenting challenge must be evaluated, like any other ground of invalidity, **against individual claims**."); and MPEP § 804. The rejection of the claims in this application over the claims of the '118, '222, '042, '374, and '348 applications fails to make any of those determinations, **including a claim-by-claim comparison and**

analysis, and, therefore, fall short for each of the above reasons alone. Here, the Examiner *only* asserted that "the claims of [the] '118, '222, '042, '374, [and] '348 [applications] encompass and/or are encompassed by the instant claims," which is simply not enough to set forth a *prima facie* case of obviousness-type double patenting. (Paper No. 0607 at 3-4).

Moreover, even when a rejection is based on a single reference or, as here, the claims of an alleged reference, there still "***must*** be a showing of a suggestion or motivation to modify the teachings of that reference." *See In re Kotzab*, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). Here, there is absolutely no reason or direction apparent from the claims of the '118, '222, '042, '374, and '348 applications, or from the office action, for ***why*** one would have been led from the claims of the '118, '222, '042, '374, and '348 applications to arrive at the currently claimed compositions in the present application. Simply stated, there is no evidence to support a conclusion that one would have been motivated and led to arrive at the combinations claimed. *Ecolochem Inc. v. Southern California Edison*, 56 USPQ2d 1065, 1076 (Fed. Cir. 2000) (*citing In re Rouffet*, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998)) (There "***must be evidence*** that a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, ***would select*** the elements from the cited prior art [reference] for combination in the manner claimed.").

Thus, it respectfully is submitted that because the rejection is deficient as a matter of fact and law, it should be withdrawn.

In addition to all of the foregoing, we note that the rejection for double patenting is provisional. Accordingly, no terminal disclaimed is required at this time.

Should this rejection be the only remaining rejection, and the claims upon which the rejection is based still pending, applicants would then explore the possibility of submitting a terminal disclaimed. Until such time, requiring a terminal disclaimer is premature. *See* MPEP §§ 804(I)(B)(1) (8th ed. Rev. 6, Sept. 2007, pp. 800-17 to 800-18).

Accordingly, for the reasons set forth above, entry of the amendments, withdrawal of the rejections, and allowance of the claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on December 11, 2007.

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Respectfully submitted,

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